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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,468

12/06/2004

Tatsuaki Suzuki

KUZ-0021

1362

7590
Licata & Tyrrell
66 East Main Street
Marlton, NJ 08053

10/26/2007

EXAMINER

PALENIK, JEFFREY T

ART UNIT

PAPER NUMBER

4133

MAIL DATE

DELIVERY MODE

10/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/517,468

Applicant(s)

SUZUKI ET AL.

Examiner

Jeffrey T. Palenik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2 Feb 2005, 12 Jun 2006, & 6 June 2007.

DETAILED ACTION

Claims 1-12 are presented and represent all of the claims under consideration.

Priority

This application is the National Stage filing of International Patent Application No. PCT/JP03/07173, filed 6 June 2003. Applicant claims priority to Japanese Foreign Application No. 2002-167514, filed 7 June 2002. Examiner finds that Applicant's filing meets the priority requirements and determines the earliest effective U.S. filing date to be 7 June 2002.

Information Disclosure Statement

Three Information Disclosure Statements filed 2 February 2005, 12 June 2006 and 6 June 2007 are acknowledged and have been reviewed.

Specification

The abstract of the disclosure is objected to because the term "µmRa" is undefined. Correction is required. See MPEP § 608.01(b).

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

Claims 6 and 7 are objected to because of the following informalities: the word "styrene" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "hard and flexible degree" in the instant claim 10 is neither clear nor sufficiently descriptive as to define precisely the attribute of the substrate being measured. If something is hard how can it be flexible? It might be solid, but hard implies that it is immovable. Clarification is required.

Claim Rejections - 35 USC § 101

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6-9, 11 and 12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 6-8 of Chono et al. (U.S. Patent No. 6,139,866) in view of claim 5 of Wick et al. (U.S. Patent 6,129,929). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 1, 6-9, 11 and 12 are broader and therefore more obvious to all that are recited in the patented claims 1 and 6-8 of Chono et al. (U.S. Patent 6,139,866), in further view of claim 5 of Wick et al. (U.S. Patent 6,129,929).

Chono et al. teaches in claim 1, a tape formulation for percutaneous administration containing the narcotic analgesic fentanyl citrate in an adhesive layer containing two components of polyisobutylene and styrene-isoprene-styrene block copolymer as well as a tackifier. Claims 6-8 teach the instant claims 6-8, 11 and 12, in that the tape formulation contains fentanyl (e.g. a narcotic analgesic), and oils and tackifiers that may be formulated into the adhesive layer. However, Chono et al. does not teach the specified surface area of the instant claim 9.

Wick et al. teaches a transdermal patch applicator system (Abstract) comprised of a polyester-based backing layer and an adhesive layer comprising a drug (claim 8). The surface area of the patch, as cited in the instant claim 9, is taught to be 20 cm² or less (claim 5).

In view of the combined teachings of the prior art, one of ordinary skill in the art would have been motivated to prepare a transdermal patch formulation comprising a silica-roughened

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backing layer and a drug-containing adhesive layer for percutaneous delivery of a drug from the adhesive layer with a reasonable expectation of success. Such would have been obvious in the absence of evidence to the contrary because Wick et al. teaches the use of various forms of silica (i.e. fumed, granulated sand), which are well known in the art as conveying surface roughness or abrasiveness the inclusion of which increase the friction between the backing and adhesive layers allowing for greater stability of the overall formulation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. (U.S. Patent 6,139,866) in view of Wick et al. (U.S. Patent 6,129,929).

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Chono et al. teaches in claim 1, a tape formulation for percutaneous administration containing the narcotic analgesic fentanyl citrate in an adhesive layer containing two components of polyisobutylene and styrene-isoprene-styrene block copolymer as well as a tackifier. Polyethylene terephthalate (PET) is taught to comprise the backing layer (column 5, lines 44-48). However, Chono does not teach surface roughness, the establishment thereof, the thicknesses of the backing and adhesive layers, the area of the patch formulation or the hard and flexible degree of the substrate.

Wick et al. teaches a transdermal patch applicator system (Abstract) comprised of a polyester-based backing layer (column 4, lines 47-57) ranging from 2-1,000 micrometers thick and an adhesive layer comprising a drug (claim 8). The formulation can be treated (e.g. "sandblasted" or sprayed) with fumed silica, reagent grade sand, or precipitated silica (column 4, lines 7-9) to convey rheological properties, although it is acknowledged that multiple functions or properties (i.e. surface roughness) can be attained through use of peripheral agents to the formulation (column 3, lines 63-65). The surface area of the patch is taught to be 20 cm² or less at claim 5. Transdermal patches are also well known in the art as possessing a general flexibility that allows for not only easier removal of the release liner, but also for easier conformation and application to the intended target (column 1, lines 19-23). As to the claimed ranges, the adjustment of particular working conditions (e.g. average roughness of a surface, thickness of a given layer, or degree of hardness and flexibility) is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

In view of the combined teachings of the prior art, one of ordinary skill in the art would have been motivated to prepare a transdermal patch formulation comprising a silica-roughened

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backing layer and a drug-containing adhesive layer for percutaneous delivery of a drug from the adhesive layer with a reasonable expectation of success. Such would have been obvious in the absence of evidence to the contrary because Wick et al. teaches the use of various forms of silica (i.e. fumed, granulated sand), which are well known in the art as conveying surface roughness or abrasiveness the inclusion of which increase the friction between the backing and adhesive layers allowing for greater stability of the overall formulation.

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-270-2966.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jeffrey T. Palenik
Patent Examiner

A handwritten signature in black ink, appearing to be 'JS' or similar, located above the printed name of Jeffrey Stucker.

JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER